

### **Remarks**

Claims 1-47 are pending in the application. Claims 38-47 are newly added. Support for the new claims is found at page 7, line 22 – page 8, line 6, and at page 19, line 25- page 20, line 4. Support for claim 46, directed to a pure (*R*) enantiomer, is found in particular at page 26, line 9. Minor amendments have been made to claims 2 and 8, to recite pharmaceutically-acceptable salts.

The specification has been amended at page 1 to update the status of the parent application as an issued patent. The specification has also been amended to correct an obvious error in the specification, in the units used for the dosage ranges disclosed in the paragraph beginning at page 27, line 1. The dosage ranges are erroneously disclosed in units of milligrams *per kilogram* per day. The units for the dosage range are corrected by the herein amendment to be *milligrams per day* without a correlation of the dosage range to the weight of a patient. The error would be obvious to one of ordinary skill in the art. The erroneous units for the dosage range would necessitate such a large dose, that one of ordinary skill would immediately recognize the information to contain an obvious error. The same amendment was made in the parent application, now U.S. Pat. 7,022,700.

Claims 1-37 are subject to restriction. Applicants elect, with traverse, the claims of Group I, comprising claims 1-13 *and new claims 38-47*, drawn to a method of increasing the absolute neutrophil count in an individual, comprising administering to said individual an effective amount of at least one compound formula I. New claims 38-47 depend directly or indirectly from claim 8, and are therefore believed to be properly grouped in Group I.

Reconsideration of the restriction requirement is requested in view of the following remarks.

Examiner alleges that the claims of Groups I-V are independent and distinct inventions, because “they have acquired a separate status in the art as shown by their different and separate subject matter for inventive effort”. Also, examiner has pointed out that a reference which anticipates one of the inventions would neither anticipate or make obvious the others.

Restriction is proper only if the pending claims represent independent or distinct inventions *and* there is a serious burden in searching and examining the entire application. MPEP § 803. Here, examiner can not show that the claims represent independent or distinct inventions, or that there is a serious burden on searching and examining the entire application. Thus, the restriction requirement is improper and should be withdrawn.

According to MPEP § 802.01, independent inventions are unconnected in design, operation or effect. Here, there is a clearly disclosed relationship between the three methods recited in Groups I-V, in that all methods relate to increasing neutrophils in the patient, and the treatment and prevention of a specific disorder, neutropenia, which is a characteristic of a reduced neutrophil count. Thus, Groups I-V are connected.

Inventions are distinct only if they are classified separately, have acquired separate status in the art when classified together, or require a different field of search (i.e., it is necessary to search for one invention in places where no pertinent art exists for others). MPEP § 801.02. Here, examiner maintains that claims I-V have acquired separate status in the art “by their different and separate subject matter for inventive effort”. Examiner provides no reasoning in support of this position.

MPEP § 803 places the burden squarely on the examiner to “provide reasons and/or examples to support conclusions” presented in a restriction requirement. See also MPEP § 808.02 (B). Examiner has not provided reasons and/or examples.

Moreover, Groups I-V are not distinct inventions because they fail to satisfy the criteria set forth in MPEP § 808.02. The claims are not separately classified. Examiner has classified each claim group in the identical class/subclass, i.e., 514/221. Each of the five groups includes the administration of a compound of formula 1, to obtain modulation of neutrophils. The claims do not require a different field of search under MPEP § 808.02 (C), because all claims carry the identical classification.

Even assuming *arguendo* that claim Groups I-V represent independent or distinct inventions, restriction is not proper because there is not serious burden on examiner in searching all claim groups. According to MPEP § 803, “a serious burden...may be prima facie shown if

the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search as defined in MPEP § 808.02". Examiner has given no explanation at all to support a serious burden for searching all claim groups. Indeed, it is believed that a search would be principally driven by the structure of formula 1 which is the administered therapeutic in common with all claim groups.

For the foregoing reasons, reconsideration and withdrawal of the restriction requirement is respectfully requested.

Respectfully submitted,

HERBERT W. HARRIS, *et al.*

BY:



DANIEL A MONACO  
Registration No. 30,480  
Drinker Biddle & Reath LLP  
One Logan Square  
18<sup>th</sup> and Cherry Streets  
Philadelphia, PA 19103-6996  
Tel.: (215) 988-3312  
Fax: (215) 988-2757  
Attorney for Applicants